REMARKS

In the Office Action, claims 1-5, 8, 9, 11-13, 15-17, 22, 23, 37, 40, 41, 43, 44 and 46-51 are rejected under 35 U.S.C. §103 from Aoyama U.S. Patent No. 6,827,963 in view of Wester U.S. Patent No. 6,589,588, C.F.R. §101.83 and St.-Onge *et al.* "Consumption of a Functional Oil Rich in Phytosterols and Medium-Chain Triglyceride Oil Improves Plasma Profiles in Men" (2003), taken together, as further evidenced by Baileys and Pelloso U.S. Patent No. 5,434,278.

Each of independent claims 1, 37 and 40 is presently amended to specify enhanced phytosterol delivery with the random interesterified triglyceride component. These claims already recite cholesterol adsorption reduction.

On page 3, the Office says that the Aoyama Formulas provide more than one possible fatty acid to be assigned to M (Medium chain) and L (Long chain). However, one reading **Aoyama** without the benefit of applicants' teaching would not so read Aoyama.

First, as observed in the previous Amendment and which has not been refuted by the Office, each of the eight (i.e. 2^3) Aoyama Formulas are the only formulas disclosed by Aoyama.

Second, on page 2 of the Office Action, it is suggested that there is no requirement in Aoyama that caprylic and capric fatty acids "must be used separately." Perhaps this statement may be literally accuate. However, looking at teaching to one of ordinary skill, Aoyama's lengthy disclosure consistently and repeatedly discloses only a single medium-chain moiety in any of the Formulas included in its compositions. The Aoyama wording is consistent in teaching lack of randomness of caprylic and capric moieties. For example, lines 40-42 in column 3 of Aoyama explicitly state that in five of the Aoyama Formulas,

> . . . RM_M is **an** acyl group of **a** saturated medium fatty chain acid having 8 to 10 carbon atoms ...

This "singularity" type of language is found throughout Aoyama and particularly in columns 3-8 of the General Description. For example:

> ... $R_MR_LR_M$ triglyceride in which **a** saturated medium-chain fatty acid having 8 to 10 carbon atoms is combined at the first and third carbon atoms of the triglyceride, and **a** monounsaturated long-chain fatty acid . . . is combined **at the second carbon** of the triglyceride.

(Aoyama, column 4, lines 46-51.)

> . . . in Formulas IV, V and VI, R_M is **an** acyl group of **a** saturated medium-chain fatty acid having 8 to 10 carbon atoms ...

(Aoyama, column 6, lines 41-43.)

> . . . Formula I, wherein R_M is acyl group of **caprylic** acid . . . Formula II and/or . . . Formula II', wherein R_M is acyl group of **caprylic** acid . . .

(Aoyama, column 6, lines 52-57.)

Third, Table I and Table IV of Aoyama teach Compositions 1, 2 and 3 according to Aoyama. They represent specific compositions having triglycerides of from four to eight of the Formulas. For example, Composition 1 has 4.6 percent "8.8.8", wherein "8" represents caprylic acid, the medium-chain component. There is no suggestion that the "8" could be a "10", for example. When it comes to the long-chain component, some flexibility is indicated by Aoyama. Thus, Composition 1 has 84.7 percent of "O.8.8" or "8.8.O" (Formula III or III') and 4.7 percent "8.O.O" or "O.O.8" (Formulas II or II'). Where "O" represents oleic acid, and 6.0 percent "other" Formulas. Composition 2 contains more Formulas, perhaps all eight of them. Of note is the 2.9 percent "8.L.8" (Formula I). Aoyama states "L" is a long-chain fatty acid other than oleic acid.

Therefore, a fair reading of Aoyama is that, while it may be possible to have the long-chain fatty acid vary from Formula to Formula, the medium-chain component is to be the same fatty acid, caprylic in these examples.

For at least these reasons, Aoyama teaches away from and does not disclose, teach or motivate one of ordinary skill in the art to arrive at applicants' claimed invention.

None of the secondary references remove these substantial and significant deficiencies of Aoyama. Applicants do not repeat in detail observations in previous Amendments concerning these secondary references, and offer the following summary observations.

St.-Onge mentions **blends** of medium chain triglyceride oil and phytosterols, without any suggestion that an MCT oil is to be interesterified with a long chain domestic oil. A blend is not an interesterification, and St.-Onge teaches nothing about random interesterified components as a means of enhancing phytosterol delivery or cholesterol reduction enhancement.

Wester has no teaching concerning random interesterification or the liquid lipid components that are claimed presently. The Office relies on the **C.F.R.** reference and **Bailey's** for showing certain properties without tying those in any way to random interesterified or phytosterol delivery enhancement or cholesterol reduction enhancement.

The present Office Action takes the position that **Pelloso** shows it is known in the art to combine different medium-chain triglycerides together for random interesterification. The Office bases its *prima facie* obviousness assertion by taking the Pelloso teachings concerning interesterification and replacing same with Aoyama's very specific teachings away as detailed hereinabove. Aoyama teaches away from randomization as applicants claim, such as with respect to the medium-chain moiety; the only specific Aoyama teachings in this regard have a single medium-chain moiety. Aoyama teaches only eight specific Formulas. Aoyama enables only enzymatic esterification, not random interesterification. The Office does not provide reasons why one of ordinary skill in the art would ignore these teachings of Aoyama and replace same with Pelloso esterification techniques.

Reconsideration and withdrawal of the §103 rejections accordingly are respectfully requested because a *prima facie* case of obviousness has not been established. Even if the Office disagrees that its *prima facie* obviousness position has been overcome, applicants respectfully assert that the alleged *prima facie* obviousness position has been overcome for the following reasons.

First, in direct response to the middle of page 4 of the Office Action, each claim is directed to showing that random interesterification is a means of enhancing phytosterol delivery. Second, in response to page 5 of the Office Action, applicants presently directly bring into the record, by way of a Declaration from one of the inventors, the clinical study reported in the 2006 Rudkowska publication, which is already of record in the present application and which has been previously discussed in prior Amendments.

The accompanying Declaration of Dilip K. Nakhasi Under Rule 132 further refutes the assertion of *prima facie* obviousness. The Office is, of course, obligated to consider all evidence of record (MPEP §716.01(a) and §2145,) The Amendments previously filed in this application and the Nakhasi Declaration evidence unexpected results in both phytosterol delivery enhancement and in cholesterol reduction enhancement. The record contains experimental data and other objective factual evidence of unexpected results and significant, practical advantages achieved by the present invention, strongly supporting a finding of unobviousness. See, for example, MPEP §7.16.02(a).

Paragraphs 6-12 of the Nakhasi Declaration provide and discuss information largely found in Example 15 of the present application. Mr. Nakhasi concludes that these test data illustrate the feature of the present claims of enhanced phytosterol delivery and that the magnitude of this enhancement shows a significant difference due to the use of the random interesterified oil composition of the present claims as the delivery vehicle for the phytosterol.

Paragraphs 13-26 of the Nakhasi Declaration concern the feature of the claims of enhanced cholesterol reduction. Included in this portion of the Nakhasi Declaration is full incorporation by reference of the 2006 Rudkowska publication reporting the results of clinical testing of the claimed invention and that shows, *inter alia*, exceptionally enhanced cholesterol reduction. The Nakhasi Declaration compares these exceptional results with the cholesterol reduction data in the record concerning this point, namely the 2003 St.-Onge publication relied upon by the Office. Applicants' reduction was half again as large as the reduction reported by St.-Onge. This alone is adequate to show unexpected

results, due to the sheer magnitude of the improvement that is largely attributed to applicants' interesterification invention versus the St.-Onge blending teaching.

Rudkowska includes specific statistical analyses comparing the claimed invention with extra virgin olive oil, with strong statistically significant differences being reported for relevant comparisons. The Nakhasi Declaration specifically states in paragraph 26 that this statistical analysis is properly extrapolated to conclude that the cholesterol reduction enhancement of applicants' claimed invention versus St.-Onge also is statistically significant.

Mr. Nakhasi provides an overall statement in paragraph 27. The enhancements and differences reported in his Declaration exhibit unexpected results in both phytosterol delivery and cholesterol reduction enhancements. The facts of record illustrate a difference in kind when compared with the references used in rejecting the claims of this application, rather than one of mere degree. Same illustrates a significant and practical advantage to an extent greater than expected from the prior art. Having an edible oil formulation enhance phytosterol delivery and cholesterol reduction is a very important practical advantage that has important health benefits.

The combination of cited references does not provide significant predictability of the magnitude of the enhancements that are strongly supported by the present record when the randomization interesterification products of the present claims are combined with phytosterols. The art provides no predictability that the randomly interesterified lipids would deliver the phytosterols with the enhanced effectiveness evident by these data. To the extent a *prima facie* case may have been presented by the Office, it has been rebutted and oversome.

Accordingly, the record provides further strong support for the unobviousness of the presently claimed invention. Reconsideration and withdrawal of the §103 rejection are believed to be in order for this additional reason.

Applicants have made an earnest endeavor to place this application into condition for allowance, and favorable consideration is respectfully requested.

Respectfully submitted

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